CREDENTIALING OF PERSONNEL INVOLVED IN HUMAN RESEARCH

1. **PURPOSE:** To establish a research service level policy that identifies the personnel who are involved in human research and/or who have a healthcare license or certification, or a degree offering the potential for a healthcare license or certification (MD, RN, BSN, Medical Technician, Audiologist, etc.), and a compliance system for credentialing such personnel. Credentialing is defined as the formal, systematic process of verifying, screening, and evaluating qualifications and other credentials (VHA Directive 2003-036). This policy requires that the education, certification(s) and healthcare license(s) of all personnel involved in human research be verified, that a Scope of Work for each individual on each IRB-approved protocol be completed by the principal investigator (PI) and signed by the PI, employee, and ACOS/R&D, and that files be maintained for all credentialed and approved employees. Such credentialing will add assurance that personnel are appropriately educated, certified, and/or healthcare licensed to effectively and safely perform human research at the Portland VA Medical Center (PVAMC). The policy will also assist in assuring only those with appropriate credentials will be involved with human research.

2. **POLICY:** Personnel involved in human research at the PVAMC must have their credentials verified, prior to working on PVAMC Institutional Review Board (IRB) approved research projects, to ensure appropriate completion of their stated education, certification(s) and/or healthcare license(s). Working on PVAMC IRB-approved research projects is contingent upon successful completion of credentialing requirements. Personnel involved in any research (basic, animal or human) who have a healthcare license or certification (e.g., medical healthcare license, nursing healthcare license, American Speech-Language-Hearing Association (ASHA) certification) or a degree offering the potential for either (e.g., MD, BSN, MSW, Medical Technician, LPN, BS Pharmacy) must be credentialed in the web-based Federal Credentialing Program for Healthcare Providers (VetPro). Those with clinical privileges are already credentialed in VetPro and therefore require no further credentialing for research, other than a Scope of Work. Those credentialed in VetPro only for research will not have privileges at PVAMC. EXCEPTION to requirement for VetPro: Residents or fellows in training must be verified via a Resident Credentials Verification Letter (RCVL) from the Medical Professional Services Office.

3. **RESPONSIBILITIES:**
   a. The **Associate Chief of Staff for Research & Development (ACOS/R&D)** is responsible for:
      (1) Completing credentialing requirements, as defined by national and local policy.
      (2) Developing and managing credentialing policies and procedures for personnel involved in human research and for all personnel with degrees that offer the potential for licensure or certification in an area of patient care at the PVAMC, whether or not such a healthcare license or certification is held or required for their research duties at PVAMC.
      (3) Ensuring that all PVAMC research personnel meeting the above criteria have completed the appropriate credentialing requirements consistent with VA policy.

   b. The **Administrative Officer for Research & Development (AO/R&D)** is responsible for:
      (1) Completing credentialing requirements as defined by national and local policy with the exception of the Scope of Work Form.
      (2) Overseeing the Research Service staff involved with the credentialing of personnel involved in research.

   c. The **Research and Development Committee (R&D) Members** are responsible for completing credentialing requirements, with the exception of the Scope of Work Form.

d. The **Research and Development Committee (R&D) Coordinator** is responsible for completing credentialing requirements.

e. The **Institutional Review Board Members** are responsible for completing credentialing requirements.

f. The **Institutional Review Board Coordinators** are responsible for:
   (1) completing credentialing requirements.
   (2) Prior to IRB review, forwarding new research project proposals and Research Personnel Change forms to the Research Assurance & Compliance Coordinator (RACC) in order to assure that all personnel on the project have successfully completed the credentialing requirements.

g. The **Research Service Human Resources Liaison** is responsible for
   (1) assuring that all research employees meet all requirements for appointment,
   (2) informing the AO for R&D of any non-compliance with appointment requirements, and
   (3) informing the Research Assurance and Compliance Coordinator (RACC) of all individuals with healthcare license or certification or a degree offering the potential for either and who require credentialing in VetPro.

h. The **Research Assurance and Compliance Coordinator (RACC)** is responsible for:
   (1) Identifying and credentialing personnel involved in human research at the PVAMC and/or who have healthcare licensure or certification or the potential for either, and credentialing as appropriate.
   (2) Requesting VetPro credentialing through Medical Professional Service or Nursing Professional Service as appropriate.
   (3) Requesting a Resident Credentials Verification Letter (RCVL) from the Medical Professional Service for physicians in training.
   (4) Informing the IRB when credentialing is incomplete for any individual on any protocol under consideration for approval.
   (5) Working with Human Resources to ensure without compensation (WOC) appointments are complete when appropriate (see 4.b.(2) below).
   (6) Monitoring personnel compliance with the credentialing requirements.
   (7) Reviewing all Scope of Work forms, signing for the ACOS/R&D, consulting with the ACOS/R&D if any questions about qualifications for any procedures.
   (8) Informing the AO/R&D and ACOS/R&D of areas of non-compliance with credentialing requirements.
   (9) Maintaining the human research section of the Personnel Database.
   (10) On a monthly basis, assuring all research appointees in human research are not the subject of regulatory action, do not have expired healthcare licenses, and have completed all credentialing requirements.
   (11) Verifying annually that healthcare license(s), certification(s), credentialing, and privileging, if applicable, are current and in good standing.
   (12) Maintaining files for all personnel working in human research and for research personnel with licensure or certification or potential for either.

i. **Personnel involved with PVAMC IRB-approved research projects** are responsible for completing credentialing requirements prior to participating in PVAMC IRB-approved research projects.

4. **PROCEDURES:**
   a. **Personnel involved in PVAMC IRB-approved human research projects who interact with patients (exceptions listed in 4.b.), collect, analyze, handle or see identifiable data, and/or have a healthcare**

license or certification or the potential for either must be credentialed. These individuals may include PVAMC employees (Title 5 and 38), Portland VA Research Foundation Employees (PVARF), Oregon Health & Science University (OHSU) employees or others with WOC appointments. Information is available on the R&D website at http://www.visn20.med.va.gov/portland/research/p-i-services/hiring/appointment-requirements.htm. Research staff involved in human research must have a VA or WOC appointment if they

(1) interact with VA research participants via telephone or in person except as listed in item b.(1) below;
(2) collect and analyze identifiable patient laboratory specimens or patient data of participants in a VA IRB-approved study;
(3) perform patient laboratory tests or work with identifiable patient data of participants in VA research studies;
(4) work in the R&D Office, i.e. ACOS/R&D, AO/R&D, R&D Committee Coordinator, IRB Coordinators, and RACC; and
(5) serve as R&D Committee and/or IRB members.

b. **Personnel involved in PVAMC IRB-approved human research projects who meet the following criteria are NOT required to complete the credentialing requirements:**
(1) Members of the research team who are strictly administrative staff, e.g., receptionist or any individuals that may have contact with a patient for scheduling purposes only.
(2) Members of the research team, e.g., biostatisticians or lab technicians who do not come to the PVAMC and do not directly interact with VA research participants or see their identifiable specimens or data (do not require a WOC appointment or credentialing).
(3) Volunteers from the community who serve on an IRB or R&D Committee. Members of groups such as Data Safety Monitoring Boards (DSMBs) who are recruited from non-VA institutions.
(4) Clinical personnel who periodically perform tests on research patients as part of their routine jobs (e.g., x-ray, nuclear medicine, or medical laboratory technologists who occasionally perform a test on a research patient as part of their routine clinical duties). However, if someone like a nurse or an x-ray tech was hired primarily to do clinical work but becomes part of a research team, he or she is affected and does have to take training and be credentialed.

c. **Individuals involved with PVAMC IRB-approved human research projects who do not meet the criteria above in item b. and are applying for either VA or WOC appointments (unpaid volunteer or paid by PVARF, OHSU, or some other outside entity) must submit the following to the R&D Office** (see R&D website "Research Appointment and Credentialing Requirements" at http://www.visn20.med.va.gov/portland/Research/p-i-services/hiring/appointment-requirements.htm**):**
(1) The applicable checklist (see http://www.visn20.med.va.gov/portland/Research/p-i-services/hiring/appointment-requirements.htm#checklists);
(2) All applicable forms available at http://www.visn20.med.va.gov/portland/Research/p-i-services/hiring/appointment-requirements.htm#forms including
- a Scope of Work form signed by the Principal Investigator for each specific protocol the employee will be working on, and
- an Education Verification Form;

d. **The RACC or other R&D Office staff designated by the ACOS/R&D will be responsible for the following:**
(1) Review of Scope of Work, follow-up concerning any questionable procedures, and obtain signature of ACOS/R&D.
(2) Verification of education for those not requiring VetPro

- through the National Student Clearinghouse or direct contact with the institution, or
- for residents and fellows, by obtaining a copy of the RCVL from Medical Professional Service.

(3) For those with healthcare license or certification or the potential for either, assuring VetPro credentialing, and if necessary, submitting a request for VetPro credentialing to Medical Professional Services or Nursing Professional Services, as applicable.
(4) Assuring through Human Resources that background checks and finger-printing are completed and appointments are finalized before approval by IRB and R&DC of personnel to work on any human research protocol.
(5) Maintaining credentialing files for all working in human research and/or who require VetPro credentialing.
(6) In the event an individual appears on any exclusionary list or is found to have an expired license, the AO/R&D and ACOS/R&D will be notified immediately. Appropriate action will be taken with consultation from Human Resources Division. The following will be checked monthly:

- The FDA Debarment List and FDA Disqualified/Restricted/Assurance List for Clinical Investigators on the FDA website.
- The Public Health Service Administrative Actions Listing.
- The R&D Personnel Database for expired healthcare licenses and verifying if the license has been renewed.

e. **Background Investigations**
Individuals involved in human research must have background investigations related to the risk level of their position. This is part of the normal VA hiring process. The Research Service will adhere to the Human Resources Division policies for background investigations, consistent with VA policy.
(1) VA employees must have a full background investigation.
(2) All individuals with a WOC appointment must be fingerprinted. If the results of the fingerprinting are questionable, a full background investigation must be completed.

f. **Record Retention**
Human research credentialing files will be maintained for a minimum of six years after the termination date of the appointment and then indefinitely until instructions are received from the Government Archives.

5. REFERENCES: VHA Directive 2006-067, Credentialing of Health Care Professionals; 1/26/2007 ORO Memo, Credentialing And Privileging Of Research Staff; Credentialing Guidance For 90 Day R&D Stand-Down; Directive 1100.19, March 6, 2001; VHA Directive 0710, May 18, 2007, Personnel Security and Suitability Program.

6. CONCURRENCES: Endorsed by the Research & Development Committee on 04/06/2009.

7. RESCISSION: HRPP: P&P No. 10, Endorsed by the Research & Development Committee on 01/26/2004, 04/04/2005 and 08/01/2005.

8. FOLLOW-UP RESPONSIBILITY: ACOS, R&D Service

Michael P. Davey, M.D., Ph.D.
ACOS, Research & Development Service